

**REMARKS**

Claims 2-5 and 13-15 are pending in the application. The amendments to the claims have been made to further clarify the present invention and conform to U.S. practice. No new matter has been inserted into the application. No new issue is raised requiring further search or consideration since the amendments to the claims serve to place the application in better condition for allowance. Accordingly, entry of the amendments to the application is respectfully requested.

**Interview Summary**

Applicants' undersigned representative thanks the Examiner for courtesies extended during the telephonic interview on July 15, 2003.

**Terminal Disclaimer**

A terminal disclaimer is submitted herewith disclaiming the terminal portion of the patent that may issue from the present application, which would extend beyond the expiration date of the patent granted on pending second Application No. 09/707,900.

**Claim Objections**

Claim 14 has been objected to because of an informality. Appropriate correction has been made as required by the Examiner. Therefore, this objection has been overcome. The Examiner has indicated in the Advisory Action of July 15, 2003 that this objection would be removed upon entry of the amendments to the claims as presented herein.

**Rejections Under 35 USC § 112, first paragraph – new matter**

Claims 2-5 and 13-15 have been rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification and introducing new matter. The Examiner has rejected claim 13 because the limitation of treating osteoarthritis with chondrocytes transfected with TGF- $\beta$  or BMP is new matter. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Applicants submit that claim 13 is directed to a method of regenerating hyaline cartilage, not to a method of treating osteoarthritis. Therefore it is believed that this rejection is misplaced.

The Examiner has also objected to the phrase “transfected/transduced” in claims 4, 5 and 13 as being new matter. The amended claims recite “transfected”. Accordingly, this objection has been overcome.

The Examiner has indicated in the Advisory Action of July 15, 2003 that this rejection would be removed upon entry of the amendments to the claims as presented herein.

**Rejections Under 35 USC § 112, first paragraph – enablement**

Claims 2-5 and 13-15 have been rejected under 35 USC § 112, first paragraph because “the specification, while being enabling for transfecting chondrocytes with DNA encoding TGF- $\beta$ 1 operably linked to a promoter, transplanting the transfected chondrocytes into a joint space of a mammal such that expression of TGF- $\beta$ 1 occurs resulting in generating hyaline cartilage, does not reasonably provide enablement for using chondrocytes encoding BMP to regenerate hyaline cartilage as broadly claimed.” Page 3, Office Action of January 29, 2003. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested. However, the amended claims are directed to chondrocyte comprising

DNA encoding TGF-  $\beta$ 1 operably linked to a promoter, which the Examiner has determined is enabled by the specification. Thus, it is believed that the rejection has been overcome.

The Examiner has indicated in the Advisory Action of July 15, 2003 that this rejection would be removed upon entry of the amendments to the claims as presented herein.

**Rejections Under 35 USC § 112, second paragraph – indefiniteness**

Claims 2-5 and 13-15 have been rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Examiner has objected to claims 4, 5 and 13 because the phrase “transfected/transduced” is unclear. The amended claims recite “transfected”. Accordingly, this objection has been overcome.

The Examiner has objected to claims 4, 5 and 13 because the phrase “chondrocyte cells” is indefinite. The amended claims recite “chondrocytes”. Accordingly, this objection has been overcome.

The Examiner has indicated in the Advisory Action of July 15, 2003 that this rejection would be removed upon entry of the amendments to the claims as presented herein.

**Rejections Under 35 USC § 103**

Claims 2-5 and 13-15 have been rejected under 35 USC § 103 (a) as being obvious over Naughton (US Patent 5,842, 477, Dec. 1, 1998) in view of Ikeda (Sept. 1998, J. Rheumatol., Vol. 25, Pg 1666-1673) and van Beuningen (Sept. 1998, Osteoarthritis and Cartilage, Vol. 6, pg 306-317). Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

The references are discussed in the previous After Final Response of May 7, 2003.

**Distinctions of the present invention over the cited references**

Naughton '477 suggests administering a composition comprising chondrocytes in the presence of scaffolding and a pharmaceutically acceptable carrier into a joint space of a mammal such that cartilage is generated.

The present invention is directed to generating hyaline cartilage by injecting a composition that consists of transfected chondrocytes and a pharmaceutically acceptable carrier thereof into a joint space of a mammal such that expression of the DNA sequence encoding TGF- $\beta$ 1 within the joint space occurs resulting in the generation of hyaline cartilage in the joint space. The closest prior art, Naughton '477, discloses administering a composition consisting of chondrocyte cells transfected with a vector encoding TGF- $\beta$ 1 in the presence of scaffolding, and a pharmaceutically acceptable carrier into a joint space of a mammal such that expression of the DNA sequence encoding TGF- $\beta$ 1 within the joint space occurs and results in the generation of hyaline cartilage in the joint space.

The present claims are distinguished over the prior art of record because the present claims use closed language to describe the composition and consists only of transfected chondrocytes and a pharmaceutically acceptable solution that excludes compositions of transfected chondrocytes, scaffolding and a pharmaceutically acceptable solution as in the prior art of record. Accordingly, the Naughton '477 reference fails to be relevant to the presently claimed invention. Ikeda and Van Beuningen fail to remedy the deficiencies in the Naughton '477 reference in their failure to disclose or suggest using the inventive composition to generate hyaline cartilage. Accordingly, the presently claimed invention is not obvious over the cited references.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to JHK Law's Deposit Account No. **502486** during the pendency of prosecution of this application. Should such additional fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

JHK Law

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By: Joseph Hyosuk Kim  
Joseph Hyosuk Kim, Ph.D.  
Reg. No. 41,425

P.O. Box 1078  
La Canada, CA 91012-1078  
Telephone: (818) 952-7400  
Facsimile: (818) 952-7424